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| 10/519,813 | 12/27/2004 | Hiroyuki Hashimoto | 1232-5570 | 5411 |
| 27123 | 7590 | 02/08/2008 | EXAMINER | |
| MORGAN & FINNEGAN, L.L.P. 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101 | | | STRZELECKA, TERESA E | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1637 | |
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| | | | 02/08/2008 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | |
|------------------------------|----------------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/519,813 | HASHIMOTO ET AL. |
| | Examiner Teresa E. Strzelecka | Art Unit 1637 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 November 2007.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-50 is/are pending in the application.
 4a) Of the above claim(s) 4,6,9,10,13,14,16-29,32,34,37,38,41,43 and 48-50 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-3,5,7,8,11,12,15,30,31,33,35,36,39,40,42 and 44-47 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>12/27/04; 9/28/06</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 1-8, 11, 12, 15, 30-47; species A) in the reply filed on November 12, 2007 is acknowledged.
2. Claims 4, 6, 9, 10, 13, 14, 16-29, 32, 34, 37, 38, 41, 43 and 48-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 12, 2007.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
4. Claims 1-3, 5, 7, 8, 11, 12, 15, 30, 31, 33, 35, 36, 39, 40, 42, 44-47 will be examined.

Information Disclosure Statement

5. The information disclosure statements (IDS) submitted on December 27, 2004 and September 28, 2006 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 12, 39, 40, 42 and 44-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Basis for the rejections is MPEP 2173.05(p)(II):

2173.05(p) Claim Directed to Product-By- Process or Product and Process

II. PRODUCT AND PROCESS IN THE SAME CLAIM

A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph. *>*IPXL Holdings v. Amazon.com, Inc.*, 430 F.2d 1377, 1384, 77 USPQ2d 1140, 1145 (Fed. Cir. 2005);< *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990) *>(< claim directed to an automatic transmission workstand and the method * of using it * held ** ambiguous and properly rejected under 35 U.S.C. 112, second paragraph>)<.

Such claims *>may< also be rejected under 35 U.S.C. 101 based on the theory that the claim is directed to neither a "process" nor a "machine," but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. *Id.* at 1551.

A) Claims 12, 40, 42, 44 and 45 are indefinite in claim 12. Claim 12 is indefinite over the recitation of: "A quality assurance method according to claim 11, wherein the probe chip carrier is a probe carrier produced by..", followed by method steps of making the product, therefore, it is not clear whether a process of quality assurance or a product or a method of making the product that is claimed.

B) Claim 39 is indefinite over the recitation of: "A quality assurance method according to claim 1, wherein the probe chip is a probe carrier produced by" followed by method steps of making the product, therefore, it is not clear whether a process of quality assurance or a product or a method of making the product that is claimed.

C) Claim 46 is indefinite over the recitation of: "A quality assurance method according to claim 11, wherein the probe chip is a probe carrier comprising:" followed by components of the

analysis and/or inspection apparatus. Therefore, it is not clear whether a method of quality assurance, or a probe chip or an apparatus is claimed.

D) Claim 47 is indefinite over the recitation of: "A quality assurance method according to claim 11, wherein the probe chip is a probe carrier produced by a producing system comprising:" followed by components of the apparatus. Therefore, it is not clear whether a method of quality assurance, or a probe chip or an apparatus is claimed.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 12, 39, 40, 42 and 44-47 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

These claims are drawn to processes and products simultaneously, therefore, since the combination of the two is non-statutory, the claims are drawn to non-statutory subject matter (see MPEP 2173.05(p)(II):

2173.05(p) Claim Directed to Product-By- Process or Product and Process

II. PRODUCT AND PROCESS IN THE SAME CLAIM

A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph. *>*IPXL Holdings v. Amazon.com, Inc.*, 430 F.2d 1377, 1384, 77 USPQ2d 1140, 1145 (Fed. Cir. 2005);< *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990) *>(< claim directed to an automatic transmission workstand and the method * of using it * held ** ambiguous and properly rejected under 35 U.S.C. 112, second paragraph>)<.

Such claims *>may< also be rejected under 35 U.S.C. 101 based on the theory that the claim is directed to neither a "process" nor a "machine," but rather embraces or overlaps two

different statutory classes of invention set forth in **35 U.S.C. 101** which is drafted so as to set forth the statutory classes of invention in the alternative only. *Id.* at 1551.

Claim Interpretation

10. In view of the indefiniteness of claims 12, 39, 40, 42 and 44-47, they will be treated as if they were method claims dependent from the method claims 1 and 11.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-3, 5, 7, 8, 11, 12, 15, 30, 31, 33, 35, 36, 39, 40, 42 and 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okamoto et al. (Nature Biotechnol., vol. 18, pp. 438-441, 2000; cited in the IDS) and Rava et al. (WO 99/39817; cited in the IDS).

Claims 1, 2, 11, 12, 15, 30, 39, 46 and 47 will be considered together in claim 2, since it is a species of claims 1, 11, 12, 15, 30, 39, 46 and 47.

A) Regarding claims 1, 2, 11, 12, 15, 30, 39, 46 and 47, Okamoto et al. teach a method comprising:

(a) a step of designing plural kinds of probes for detecting a target substance (Fig. 4);
(b) a step of synthesizing the designed plural probes (page 440, second paragraph; page 441, second paragraph; Okamoto et al. do not specifically teach synthesizing the probes, but since they had them, they inherently had to be synthesized.);

(c) a step of individually purifying the synthesized plural probes (page 440, second paragraph; page 441, second paragraph; Okamoto et al. do not specifically teach purifying the probes, but since they had them, they inherently had to be synthesized and purified after synthesis.);

(d) a step of obtaining probe information on each purified probe (page 440, second paragraph; page 441, second paragraph; Okamoto et al. do not specifically teach obtaining probe information, but since they had them, they inherently had to be synthesized and purified after synthesis, therefore, they knew they had purified probes, i.e., obtained information about the probes.);

(e) a step of judging "good" or "not good" state of synthesis and purification in each purified probe according to the obtained probe information and a predetermined criterion (page 440, second paragraph; page 441, first and second paragraph; page 438, 7th paragraph; Fig. 2; where the probes' integrity was determined using HPLC after deposition onto a surface);

(f) a step of repeating the foregoing steps (b) to (e) on the purified probe of which state of synthesis and purification is judged as "not good", thereby obtaining "good" state of synthesis and purification in all the purified probes Okamoto et al. teach repeating the steps with different probes (page 440, second paragraph; page 441, first and second paragraph; page 438, 7th paragraph; Fig. 2).);

(g) a step of individually dissolving each purified probe judged as "good" in a solvent for ejection to a carrier, based on at least a part of the probe information obtained in (d), in a predetermined concentration and storing each obtained probe solution in an individual storing container (page 438, paragraphs 6 and 7; page 439, second paragraph);

(h) a step of transferring each probe solution stored in the storing container to another container equipped in an apparatus for deposition onto the carrier (page 438, 7th paragraph; page 439, second paragraph; inherent in the fact that dissolution was not done in the ink-jet printer);

(i) a step of applying a surface treatment for fixing the probe to the carrier (page 438, last paragraph; page 439, first paragraph; page 441, fourth paragraph);

(j) a step of depositing the probe solution onto a treated surface of the carrier by a method including following steps, thereby forming a plurality of mutually independent probe fixation areas;

(j-2) a step of depositing at least one selected from plural probe solutions onto the carrier judged as "good" so as to form a probe deposition area independent for each probe solution (page 439, second and third paragraphs);

(j-3) a step of executing an inspection, concerning a formed state of the probe deposition area, on the carrier on which the probe deposition area is formed, and judging "good" or "not good" state of the deposition according the result of the inspection and a predetermined criterion (page 439, paragraphs 4, 7; Fig. 3; where the spot distribution and shape were examined);

(j-4) a step of executing, on the carrier having the probe deposition area judged as "good", a fixation of the probe to the surface of the carrier thereby obtaining a probe carrier (page 439, second and third paragraphs);

(j-5) a step of executing an analytical inspection on the probe in at least one of the plural probe fixation areas constituted of probes fixed on the carrier; and (j-6) a step of judging "good" or "not good" state of the produced probe carrier according to the result of the analytical inspection and a predetermined criterion (page 439, paragraphs 4, 7; Fig. 3; where the spot distribution and shape were examined, also Fig. 5 and 6, where the hybridization reactions to proper probes were examined).

Regarding claims 3, 31 and 40, Okamoto et al. teach nucleic acid probes (page 440, second paragraph; Fig.4).

Regarding claims 5, 33 and 42, Okamoto et al. teach detecting purity of nucleic acid probes (page 440, second paragraph; page 441, first and second paragraphs).

Regarding claims 7, 35 and 44, Okamoto et al. teach covalent bonding of nucleic acid probes (page 438, last paragraph; page 439, first paragraph).

Regarding claims 8, 36 and 45, Okamoto et al. teach inkjet apparatus with single and plural ink jet nozzles (page 439, paragraphs 2 and 8).

B) Regarding step (j-1), Okamoto et al. do not teach inspecting the carrier after the surface treatment.

C) Regarding claims 1, 2, 11, 12, 15, 30, 39, 46 and 47, Rava et al. teach quality control process for manufacturing biochips (page 1, lines 1-16; page 6, lines 6-18; page 14, lines 12-23; page 15, lines 1-2). Rava et al. specifically teach that each of the steps of array manufacturing can be subject to a quality control before further processing (page 17, lines 5-8) and testing of substrates after they were coated with xilane but before attachment of oligonucleotides (page 17, lines 9-14).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used the methods of quality control of Rava et al. in the chip production process of Okamoto et al. The motivation to do so, is provided by Rava et al. (page 1, lines 6-13):

“Typically, the quality control testing of the items to be manufactured is performed at the point the item of manufacture is completed. In the event that the representative sample of items fails the requisite standards, all the items that had been processed with samples which would be expected to have similar defects are rejected. When the basis for rejection exists because of a process which

occurred several steps prior to the completion of the product, the further processes were performed unnecessarily, at a great expense of time and money."

13. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
Art Unit 1637

Teresa Strzelecka
8/1/08